

REMARKS

This Amendment is submitted in reply to the non-final Office Action mailed on May 28, 2010. No fees are due herewith this Amendment. The Director is authorized to charge any fees that may be required, or to credit any overpayment to Deposit Account No. 02-1818. If such a withdrawal is made, please indicate the Attorney Docket No. 3712036-00755 on the account statement.

Claims 1-7 and 12 are pending in the application. Claims 8-11 and 13-14 were previously withdrawn. In the Office Action, Claims 1, 3-4 and 6 are objected to. Claims 1-7 and 12 are rejected under 35 U.S.C. §112. Claims 1-4, 6, 7 and 12 are rejected under 35 U.S.C. §102. Claims 1-7 and 12 are rejected under 35 U.S.C. §103. In response, Claims 1 and 3-6 have been amended and Claim 12 has been canceled without prejudice or disclaimer. The amendments are solely for clarification purposes, do not add new matter, and are supported in the specification at, for example, the Abstract. In view of the amendments and/or for at least the reasons set forth below, Applicants respectfully request that the rejections be reconsidered and withdrawn.

In the Office Action, Claims 1, 3-4 and 6 are objected to for reasons of informalities. In response, Applicants have amended Claims 1 and 3-6 solely for clarification purposes and not to avoid any prior art. For at least these reasons, Applicants respectfully request that the objections to Claims 1, 3-4 and 6 be reconsidered and withdrawn.

In the Office Action, Claims 1-7 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, the Patent Office asserts that "because from the way claim 1 is written it is not exactly clear how the claimed characteristics, pH and log-unit of the living microorganisms in the product during the storage, should change." See, Office Action, page 3, lines 14-18. Applicants respectfully disagree.

The standard for determining whether the definitiveness requirement is met under 35 U.S.C. § 112, second paragraph is "whether those skilled in the art would understand what is claimed when the claim is read in light of the Specification." *Orthokinetics Inc. v. Safety Travel Chairs Inc.*, 1 USPQ 2d 1081-1088 (Fed. Cir. 1986). "If the claims, read in light of the Specification, reasonably apprise those skilled in the art both of the utilization and scope of the

invention, and if the language is as precise as the subject matter permits, the Courts can demand no more.” *North American Vaccine Inc. v American Cyanamid Co.*, 28 USPQ 2d 1333, 1339 (Fed. Cir. 1993). By statute, 35 U.S.C. 112, Congress has placed no limitations on how an applicant claims his invention, so long as the specification concludes with claims which particularly point out and distinctly claim that invention.” *In re Pilkington*, 162 USPQ 145, 148 (CCPA 1996).

As is described in detail in the specification, the presently claimed products are shelf-stable because the microorganisms contained therein are able to survive for several months at room temperatures due to their inability to metabolize nutrients contained in the product. See, specification, Abstract. Indeed, the fact that many probiotic bacteria possess an anaerobic metabolism imposes specific technical requirements on all process and product levels between a starting culture and a consumable product suitable to deliver said bacterium in sufficiently high concentration to a human or animal. See, specification, lines 31-34. Further, the mere fact that living bacteria are metabolically active--even at chilled temperatures--imposes problems: ingestible carriers of probiotics often sustain degradation by the bacterial activity, which may render the carrier completely unpalatable. See, specification, page 1, line 36-page 2, line 2.

One way of delivering a probiotic is the preparation of a material, which was fermented by the probiotic. This is the case, for example, with yoghurts that were obtained from fermenting milk with micro-organisms. An advantage of these products is that they are relatively stable when chilled, due to the low pH of the product after fermentation. However, the acid produced by the fermenting activity of the probiotic does not correspond to every consumer's taste. In addition, these products still have to be chilled. See, specification, page 2, lines 21-27.

As is further described in the specification, the products according to the present disclosure may be fermented products, which are obtained, for example, by fermenting a medium, heat treating or pasteurizing the medium to reduce bacterial load, and, at the same time, kill the fermenting bacteria. Then the fermented products could be supplemented with a micro-organism, which will not further grow on the fermented medium. For example, the products may be a yoghurt, which is heat-treated and to which micro-organisms which are not able to grow on

the fermented, heat-treated product are added, in order to obtain products that fulfill the features of the present claims. See, specification, page 6, lines 20-32.

Thus, Applicants respectfully submit that the skilled artisan would immediately appreciate that Claim 1 is directed to a product that is shelf-stable for at least 1 month at 10°C, during which time the product experiences one of a decrease in pH of less than 2 points, and a decrease in the amount of living microorganisms of less than 2 log-units. In other words, the specification is very clear that fermentation of a carbohydrate by a microorganism can cause problems with delivery of a sufficiently high concentration of bacterium to a human or animal and palatability of a final product. As such, by preventing additional fermentation of a carbohydrate by a microorganism, Applicants are able to provide shelf-stable products with surprising characteristics.

For at least these reasons, Applicants respectfully submit that Claims 1-7 fully comply with the requirements under 35 U.S.C. §112, second paragraph.

Accordingly, Applicants respectfully request that the rejection of Claims 1-7 under 35 U.S.C. §112, second paragraph, be reconsidered and withdrawn.

In the Office Action, Claim 12 is rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly define the metes and bounds of the subject matter which applicant regards as the invention. See, Office Action, page 3, line 20-page 4, line 7. In response, Applicants have canceled Claim 12 without prejudice or disclaimer.

For at least these reasons, Applicants respectfully submit that the rejection of Claim 12 under 35 U.S.C. §112, second paragraph, is rendered moot.

Accordingly, Applicants respectfully request that the rejection of Claims 12 under 35 U.S.C. §112, second paragraph, be reconsidered and withdrawn.

In the Office Action, Claims 1-4, 6, 7 and 12 are rejected under 35 U.S.C. §102(b) as being anticipated by WO 00/53202 to Reniero et al. ("*Reniero*"). Applicants respectfully submit that *Reniero* is deficient with respect to the present claims.

Currently amended independent Claim 1 recites, in part, liquid products comprising microorganisms, having a shelf-life of at least 1 month at 10°C, during which period at least one characteristic chosen from the group consisting of a pH of the product decreasing less than 2 points and an amount of living microorganisms decreasing less than 2 log-units occurs and which

is free of carbohydrates that can be metabolized by the microorganisms. As discussed in detail in the specification, prior art products having microorganisms may suffer from a number of deficiencies including, for example, the inability to provide a sufficient concentration of the microorganism to the subject, or unpalatability. However, Applicants have surprisingly found that providing microorganisms in a product that does not contain carbohydrates that may be digested by the microorganism results in a product that is shelf-stable for extended periods of time and provides a sufficient amount of microorganisms to the subject. In contrast, Applicants respectfully submit that *Reniero* fails to disclose or suggest each and every element of the present claims.

For example, *Reniero* fails to disclose or suggest liquid products comprising microorganisms, having a shelf-life of at least 1 month at 10°C, during which period at least one characteristic chosen from the group consisting of a pH of the product decreasing less than 2 points and an amount of living microorganisms decreasing less than 2 log-units occurs and which is free of carbohydrates that can be metabolized by the microorganism as required, in part, by the present claims. Instead, *Reniero* is entirely directed to the prevention of diarrhoea brought about by rotaviruses and pathogenic bacteria. See, *Reniero*, Abstract. Indeed, *Reniero* expressly discloses that the microorganisms (e.g., lactic acid bacterium) used in the compositions must be capable of growing in the presence of bile salts in a composition of up to about 0.4% and may essentially prevent invasion of epithelial cells by rotaviruses. See, *Reniero*, page 3, lines 27-31. At no place in the disclosure does *Reniero* disclose or suggest liquid products comprising microorganisms, having a shelf-life of at least 1 month at 10°C, during which period at least one characteristic chosen from the group consisting of a pH of the product decreasing less than 2 points and an amount of living microorganisms decreasing less than 2 log-units occurs and which is free of carbohydrates that can be metabolized by the microorganism as required, in part, by the present claims.

The Patent Office asserts that *Reniero* discloses lactose and a microorganism that does not metabolize lactose (e.g., *L. casei* CNM I-2116). See, Office Action, page 5, lines 11-14. Along the same lines, however, Applicants respectfully submit that the Patent Office cannot ignore certain portions of *Reniero* that disclose the use of microorganisms in combination with carbohydrates that may be metabolized by those microorganisms. For example, in addition to *L.*

casei, *Reniero* also discloses the use of yeast and tryptose phosphate broth. See, *Reniero*, page 10, line 31-page 11, line 6. Tryptose phosphate broth is a versatile nutritionally rich buffered glucose broth. Further, the skilled artisan would immediately appreciate that glucose is metabolized by both lactose and yeast. As such, Applicants respectfully submit that *Reniero* is not free from any carbohydrates that may be metabolized by the microorganisms.

Further, *Reniero* expressly discloses in Figure 2 the acidification of *L. casei* ST11 in growth media wherein the amount of living microorganisms decreases by more than 2 log-units. Indeed, each of the curves in Figure 2 demonstrates a starting point of 6.5 and an ending point of 4.5 or lower. See, *Reniero*, Figure 2. This is in direct contrast to the present claims, which require, in part, liquid products comprising microorganisms, having a shelf-life of at least 1 month at 10°C, during which period at least one characteristic chosen from the group consisting of a pH of the product decreasing less than 2 points and an amount of living microorganisms decreasing less than 2 log-units occurs.

For at least the reasons discussed above, Applicants respectfully submit that Claims 1-4, 6, 7 and 12 are novel, nonobvious and distinguishable from the cited reference.

Accordingly, Applicants respectfully request that the rejection of Claims 1-4, 6, 7 and 12 under 35 U.S.C. §102 be reconsidered and withdrawn.

In the Office Action, Claims 1-7 and 12 are rejected under 35 U.S.C. §103 as being unpatentable over *Reniero* in view of Current Issue Intest. Microbila., 2002, Vol. 3, p. 39-48 to Kailasapathy ("*Kailasapathy*") and further in view of U.S. Patent No. 5,382,438 to Hottinger et al. ("*Hottinger*"). Applicants respectfully submit that the cited references are deficient with respect to the present claims.

As discussed above, currently amended independent Claim 1 recites, in part, liquid products comprising microorganisms, having a shelf-life of at least 1 month at 10°C, during which period at least one characteristic chosen from the group consisting of a pH of the product decreasing less than 2 points and an amount of living microorganisms decreasing less than 2 log-units occurs and which is free of carbohydrates that can be metabolized by the microorganisms. As is further discussed above, *Reniero* fails to disclose or suggest each and every element of the present claims. Because the Patent Office admits that *Reniero* fails to disclose or suggest each and every element of the present claims, see, Office Action, page 6, lines 15-16, the Patent

Office cites *Kailasapathy* and *Hottinger*. Applicants respectfully submit that *Kailasapathy* and *Hottinger* fail to remedy the deficiencies of *Reniero* because *Kailasapathy* and *Hottinger* also fail to disclose or suggest each and every element of the present claims.

For example, *Kailasapathy* and *Hottinger* fail to disclose or suggest liquid products comprising microorganisms, having a shelf-life of at least 1 month at 10°C, during which period at least one characteristic chosen from the group consisting of a pH of the product decreasing less than 2 points and an amount of living microorganisms decreasing less than 2 log-units occurs and which is free of carbohydrates that can be metabolized by the microorganism as required, in part, by the present claims. Instead, *Kailasapathy* is not even directed to analogous subject matter since *Kailasapathy* is directed entirely to encapsulation and immobilization of microorganisms. Despite the fact that *Kailasapathy* discloses microorganisms, *Kailasapathy* is not related to present claims in any other manner. Indeed, the skilled artisan would not look to *Kailasapathy* to remedy *Reniero* to arrive at the present claims merely because *Kailasapathy* mentions microorganisms. Applicants submit that such a combination is extremely attenuated and improper since *Kailasapathy* is not analogous art.

Hottinger is entirely directed to yogurt that is prepared by inoculating and fermenting a milk with a symbiotic combination of both *S. thermophilus* and *L. bulgaricus*. See, *Hottinger*, Abstract. However, *Hottinger* expressly disclose that “the ‘L. bulgaricus’ mutant is apparently incapable on its own of fermenting lactose although, cultured in a milk in symbiosis with ‘S. thermophilus’, it is capable of acidifying this milk almost as well as the mother strain from which it has come.” See, *Hottinger*, column 3, lines 9-17. As such, Applicants respectfully submit that the entire invention of *Hottinger* is directed to the use of *S. thermophilus* and *L. bulgaricus* in symbiosis to ferment a carbohydrate. This is in direct contrast to the present claims, which require the products to be free of carbohydrates that may be fermented by a microorganism.

For at least the reasons discussed above, Applicants respectfully submit that Claims 1-7 and 12 are novel, nonobvious and distinguishable from the cited reference.

Accordingly, Applicants respectfully request that the rejection of Claims 1-7 and 12 under 35 U.S.C. §103 be reconsidered and withdrawn.

For the foregoing reasons, Applicants respectfully request reconsideration of the above-identified patent application and earnestly request an early allowance of the same. In the event there remains any impediment to allowance of the claims which could be clarified in a telephonic interview, the Examiner is respectfully requested to initiate such an interview with the undersigned.

Respectfully submitted,

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BY  _____

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